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#5 JM 7/24/01

PATENT
UMD 1-042

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of:
Kiron M. Das

Group Art Unit: 1642

Serial No.: 09/512,515

Examiner: Brenda Brumback

Filed: 24 February 2000

For: **IMMUNOASSAY METHOD FOR THE DIAGNOSIS OF GASTRIC INTESTINAL METAPLASIA ASSOCIATED WITH GASTRIC CARCINOMA**

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE PURSUANT TO 37 C.F.R. SECTION 1.143

Sir:

This Response pursuant to 37 C.F.R. Section 1.143 is in reply to the Examiner's Action dated 14 June 2001 in the above-identified patent application in which claims 1-29 were subjected to a restriction requirement.

Applicants request that the Examiner consider the following Response and withdraw the pending restriction requirement.

CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. SECTION 1.8

I hereby certify that this correspondence is being deposited, pursuant to 37 C.F.R. Section 1.8, with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this 13th of July, 2001.

By Richard R Muccino 13 July 2001
Richard R. Muccino date
Reg. no. 32,538
Attorney for Applicant(s)

RESPONSE

The Examiner has required restriction of the claims in the present application pursuant to 35 U.S.C. Section 121. Specifically, the Examiner states that restriction to one of the following groups is required. (The grouping of claims below is corrected in accord with applicant's telephone conference with the Examiner on 12 July 2001.)

I. Claims 1-20, which are drawn to *in vitro* immunoassay methods for diagnosing human gastric intestinal metaplasia, classified in class 435, subclass 7.23.

II. Claims 21-29, which are drawn to methods of *in vivo* diagnosis, classified in class 424, subclass 9.341.

The Examiner states that the inventions are distinct, each from the other because inventions I and II are not capable of use together and they have different method steps, different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). The Examiner maintains that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants elect to prosecute the claims of Group I, claims 1-20. Applicants traverse the Examiner's restriction requirements.

Applicants' invention, as defined in claims 1-10, pertains to an *in vitro* immunoassay method for diagnosing human gastric intestinal metaplasia. The

method comprises the steps of (a) contacting a gastric tissue sample of a subject suspected of having human gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen; and (b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human gastric intestinal metaplasia.

Applicants' invention, as defined in claims 11-20, pertains to an *in vitro* immunoassay method for screening for human gastric intestinal metaplasia, thereby indicating a predisposition for gastric carcinoma. The method comprises the steps of (a) contacting a gastric tissue sample of a subject suspected of having human gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen; and (b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human gastric intestinal metaplasia.

Applicants' invention, as defined in claims 21-29, pertains to an *in vivo* immunoassay method for diagnosing human gastric intestinal metaplasia. The method comprises the steps of (a) administering to a human, suspected of having human gastric intestinal metaplasia, the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen and is tagged with an isotope; and (b) detecting

immunoreactivity between the human gastric intestinal metaplasia cells and the monoclonal antibody by external scanning, such immunoreactivity indicating a positive diagnosis of human gastric intestinal metaplasia.

M.P.E.P. Section 803 states that there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent ... or distinct as claimed; and

(2) There must be a serious burden on the Examiner if restriction is not required...(emphasis added, citations omitted).

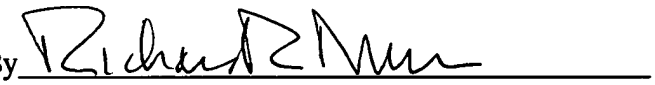
If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions, M.P.E.P. Section 803. Applicants contend that the search and examination of the present application can be made without serious burden and request the Examiner to examine it on the merits.

Hence, applicants contend that the search and examination of claims 1-10, which pertain to an *in vitro* immunoassay method for diagnosing human gastric intestinal metaplasia, claims 11-20, which pertain to an *in vitro* immunoassay method for screening for human gastric intestinal metaplasia, thereby indicating a predisposition for gastric carcinoma, and claims 21-29, which pertain to an *in vivo* immunoassay method for diagnosing human gastric intestinal metaplasia, can be made without serious burden to the Examiner and therefore restriction is not proper. In view of the foregoing Response, applicants request reconsideration pursuant to 37 C.F.R. Section 1.143 of the Examiner's position

requiring restriction so that all of the claims can be examined in this single application thus helping to expedite prosecution of this application.

Applicants request the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments which might be most expeditiously handled by a telephone conference. Applicants' attorney authorizes the Examiner to charge Deposit Account 13-4822 if there are any additional charges in connection with this Response

Respectfully submitted,
Kiron M. Das.

By 

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